STATSEAL.

510(k) SUMMARY

JUL 0 9 2013

This section contains the following information:

510(k) SUMMARY

1. Sponsor

Biolife, LLC

8163 25th Court East

Sarasota, FL 34243

Telephone: 941-360-1300

Fax: 941-360-1310

Registration Number: 1066421

Contact Person: Claudia A. Masselink

2. Date Summary was Prepared

May 6, 2013

3. Device Information

Proprietary Name:	StatSeal Disc
Common Name:	Hemostatic Disc Wound Dressing
Classification Name:	Dressing, Unclassified

4. Predicate Device

Biolife, L.L.C.; PRO QR (Quick Relief)® Powder (K080210)

Hemaderm (K021678)

5. Device Description

Components – StatSeal Disc is composed of two main components: Potassium ferrate, and hydrophilic polymer.

Mechanism of Action – StatSeal Disc achieves its principle intended action (hemostasis) by creating a physical barrier or seal to the blood flow.

6. Intended Use

OTC:

StatSeal Disc is intended for OTC use as a topical dressing for bleeding control associated with minor wounds, for temporary external control of minor bleeding from minor wounds, minor cuts, minor lacerations and minor burns.

Rx:

StatSeal Disc is intended under the care of a health care professional for external temporary control of bleeding from percutaneous needle access, vascular access sites and percutaneous catheters.

7. Substantial Equivalence

StatSeal Disc has substantially equivalent claims to Biolife, L.L.C.; PRO QR (Quick Relief)® Powder (K080210) predicate, in that it is indicated for topical application as an aid in the control of minor bleeding wounds. StatSeal Disc uses the same safe and effective technology as PRO QR (Quick Relief)® Powder (K080210). The subject and predicate are identical devices. They are made from materials which have demonstrated satisfactory biocompatibility, are highly absorbent for collecting body fluids, and are sterile, single use devices.

StatSeal Disc has identical claims to the HemaDerm (K021678) predicate in that it is intended to be applied to a vascular access site to control bleeding. Both HemaDerm and StatSeal Disc share a mechanism of action i.e. both products rapidly dehydrate blood.

8. Performance Testing

Biocompatibility Testing:

All required biocompatibility testing was conducted on PRO QR Powder (K080520) with no adverse results. StatSeal Disc and PRO QR Powder have identical composition therefore no change in biocompatibility is expected.

In vitro Testing:

Absorption Study, Scanning Electron Microscopy (SEM) Comparison, Hemostatic Properties of StatSeal Disc, Disintegration Study, Friability Study.

In-vivo Testing:

A comparative Study Evaluating Vascular Access Hemostasis Properties of StatSeal Disc in GottinGen Minipigs.

9. Conclusion

StatSeal Disc has the same intended use as the PRO QR Powder and HemaDerm predicate devices. StatSeal Disc raises no issues of safety or effectiveness. StatSeal Disc induces hemostasis by fluid dehydration, protein coagulation and agglomeration.

Biolife, LLC believes that, StatSeal Disc is safe and effective for temporary external control of minor bleeding from minor wounds, and for temporary external control of bleeding from percutaneous needle access, vascular access sites and percutaneous catheters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

July 9, 2013

Biolife, L.L.C.
% Ms. Claudia Masselink
Director Quality Assurance
8163 25th Court East
Sarasota, Florida 34243

Re: K130324
Trade/Device Name: StatSeal Disc
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 09, 2013
Received: May 13, 2013

Dear Ms. Masselink:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATSEAL.

510(k) Number : K130324

Device Name: **StatSeal Disc**

Indications for Use:

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Prescription Use ___x___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___x___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K130324